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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,142	02/15/2002	Robert John D'Amato	05213-3000 (43170-269288)	2351
23370	7590	10/16/2003	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1616	10
DATE MAILED: 10/16/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/077,142

Applicant(s)

D'AMATO ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-40 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **First Office Action on the Merits**

#### ***Election/Restrictions***

1. Claims 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of cell mitosis (angiogenesis), does not reasonably provide enablement for inhibition of neovascularization not due to angiogenesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction

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presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The claimed invention is a method of inhibiting neovascularization. However, according to the present specification, page 5, lines 18-21, the claimed compounds have anti-mitotic activity which was "evaluated by testing their ability to inhibit the proliferation of new blood vessel cells (angiogenesis)". Thus, the present specification is equating angiogenesis to anti-mitosis. Angiogenesis is the process of neovascularization from pre-existing blood vessels. The term "neovascularization" is broader than angiogenesis and includes proliferation of blood vessels in tissue not normally containing them or the proliferation of blood vessels of a different kind than usual in a tissue. The present specification lacks examples of proliferation of blood vessels in tissues not normally containing them or of a different kind than usual in a tissue and thus, does not provide guidance to enable to the skilled artisan to practice the claimed invention commensurate in scope with the instant claims. The skilled artisan would have to first search the literature for an assay that would be useful in the determination of the ability of compounds to inhibit blood vessel proliferation in tissues not normally containing them or the proliferation of blood vessels of a different kind than usual in a tissue. He would then have to test the numerous compounds encompassed by the claimed invention in said assays in order to determine that ability to inhibit blood

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vessel proliferation as defined by the term "neovascularization". Said determination would result in undue experimentation.

It is suggested that the claimed invention be limited to angiogenesis or the specific diseases as disclosed by the present specification.

4. Claims 29-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims fail to comply with the written description requirement because of the inclusion of subject matter not described by the present specification. For example, the recitation of (a) inhibition of neovascularization and (b)  $R_1$  as a straight, branched, or substituted alkyl with **up to 10 carbons or a heterocycle**. However, the present specification defines (a) the inhibition of cell mitosis and equates said to inhibition of angiogenesis not neovascularization and (b)  $R_1$  as a substituted or unsubstituted alkyl, alkenyl or alkynyl group of **up to 6 carbons not up to 10 carbons or a heterocycle**. Therefore, the present specification does not convey to the skilled artisan that the inventor(s), at the time of filing of the application, had possession of the claimed invention.

Note: The above are only examples of subject matter not described by the present specification. Please note the definition of other R groups.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 29, 30, 32, 33, 35, 36, 38 and 39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-62 of copending Application No. 10/280,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass inhibition of angiogenesis in a mammal. The latter application differs from the present invention by reciting a more limited invention, i.e., treatment of specific mammalian diseases characterized by undesirable angiogenesis utilizing 2-methoxy-estradiol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 29-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-62 of

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compending Application No. 10/080,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass inhibition of cell mitosis/angiogenesis in a mammal. The latter application differs from the present invention by reciting a more limited invention, i.e., treatment of mammalian diseases characterized by undesirable cell mitosis, i.e., angiogenesis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 29-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 7 of U.S. Patent No. 5,504,074. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to treatment of mammalian diseases characterized by undesirable angiogenesis. The instant invention differs from the cited patent by recitation of "inhibiting neovascularization" which includes inhibition of proliferation of blood vessels not encompassed by angiogenesis.

9. Claims 29-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 8 of U.S. Patent No. 5,661,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to treatment of mammalian diseases characterized by undesirable cell mitosis. The instant invention differs from

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the cited patent by recitation of "inhibiting neovascularization" which includes inhibition of proliferation of blood vessels not encompassed by angiogenesis.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 29, 30, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Seegers et al.

Seegers et al. teach the antimitotic properties of 2-methoxyestradiol (see the entire article, especially Abstract and pages 807-809). The method of use taught by the reference is encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 31-34 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seegers et al.



Seegers et al. teach the antimitotic property of 2-methoxyestradiol (see the entire article, especially Abstract and pages 807-809).

The instant claims differ from the reference by reciting inhibition of ocular neovascularization. However, the ordinary artisan in the art at the time of the present invention would have the reasonable expectation that 2-methoxyestradiol would inhibit mitosis in any tissue and, thus, would inhibit cell mitosis in ocular tissue. The motivation to utilize 2-methoxyestradiol in inhibition of ocular neovascularization is based on the teachings by Seegers of the antimitotic property of the compound and the expectation by the skilled artisan that 2-methoxyestradiol would exhibit antimitotic activity irrespective of the tissue.

#### ***Telephone Inquiry***


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
October 8, 2003